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May 6, 2005

PMPRB
Box L40
Standard Life Centre
333 Laurier Avenue West
14th floor
Ottawa, Ontario
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Re: Baxter Corporation's Input With Regard to
"Price Increases for Patented Medicines: Discussion Paper"

In response to the PMPRB's request for input in the above noted Discussion Paper, the following is respectfully submitted to the Board, by Baxter Corporation.

Baxter Corporation supports and upholds the Patent Act established in 1987, and its subsequent C-22 and C-91 Amendments, through the agency of the Patented Medicine Prices Review Board (PMPRB), whose mandate is to review prices of patented medicines sold in Canada to ensure they are not excessive.

The weight of the PMPRB, combined with other market/sector factors, has been successful in providing price stability and together, have ensured appropriate but not excessive price trending for the last 17 years. As stated in the PMPRB's Appendix to the current discussion paper "*Since 1994, …prices in Canada have remained below the international median and in line with policy objectives.*"

It should be noted that any discussion of pricing should also include other significant factors which serve to control price increases in Canada including but not restricted to:

- The competitive forces within the market in Canada;
- The role of the provincial formularies where cost/benefit is a significant decision point in the listing for reimbursement of a pharmaceutical and often the restriction of use of the pharmaceutical for covered patients to specific uses based on evidence-based clinical review;
- The role of hospital formularies where drugs will only be approved for use in the hospital if they show sufficient clinical benefit over other treatment modalities, with the cost of treatment being a major factor in the decision-making process; and
- The common drug review process where both price **and** clinical benefit are reviewed.

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All of these processes, working within the framework of the PMPRB guidelines and powers, combine to ensure patented medicines are rigorously analyzed and fairly priced in the Canadian market. As such, the current process has provided and will continue to provide, clear guidelines and processes for price increases that are reasonable.

As stated by the PMPRB itself, price stability has been achieved, proof that over the last 17 years, this system of checks and balances has worked. The price increases of one year (2004) have been negatively extrapolated forward, to "*raise concerns that perhaps we might be seeing the first signs of a change,"* This is, to our way of thinking, somewhat premature, as one year does not constitute a trend. Monitoring should no doubt continue, but as no trend has yet been established, it would be irresponsible in our view to base a policy change on this limited, and potentially misleading information.

With regard to the five questions specifically asked within the Discussion Paper, Baxter Corporation respectfully submits the following answers.

1. **Should they continue to allow for automatic (i.e., without prior approval) price increases?**

   Yes. The current system works, without any additional or incremental process, or administration by industry or additional costs to maintain the PMPRB review system being necessary.

2. **Are there considerations other than, or in addition to, the CPI that should be used to review price increases?**

   Additional considerations should include the cost of raw materials, excessive costs to manufacture and the cost of achieving increasingly significant regulatory compliance hurdles.

3. **How often should price increases occur? (e.g., every year, once every 3-5 years, only after a certain introductory period, when justified?)**

   As per the existing process, companies should have the opportunity to increase price at least once a year, based on CPI and other market variables. (For example, market variables such as competition naturally control the extent to which price increases are implemented.)

4. **If justification is required, what criteria should be considered?**

   Baxter does not believe justification should be required, as current market dynamics include justifications as dictated by provincial or hospital formularies, competitive pressures, etc., which are already part of this decision paradigm. Justification would also add significant cost to both the PMPRB and patented medicine manufacturers operating in Canada.

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5. Given that the CPI is established in the Patent Act as a factor to be considered by the PMPRB, do you have any comments on its appropriate application in future Guidelines?

CPI is an objective, validated indicator used by a broad number of industries and organizations to describe what is a fair and reasonable price increase. Given its broad and accepted use, it makes sense to continue using it within this framework.

In Conclusion:

In short the current system as established by the PMPRB works.

- Price increases have been below changes in the CPI;
- Price increases have been consistently below the U.S. index; and
- Canadian prices compare very favourably to international comparator countries.

Thank you for the opportunity to comment and provide our perspective.

Sincerely,

Barbara Leavitt
President
Baxter Corporation